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**Welcome to the 5<sup>th</sup> meeting of the  
WEO CRCSC  
Expert Working Group  
'FIT for Screening'**

**Hilton Chicago Hotel  
Chicago**

**Friday 2 May 2014, 08:30 – 11:30**

**Chair : Stephen P. Halloran**  
**EWG Committee Support – Dr Helen Seaman**

**Founding members:**  
Jim Allison, University of California San Francisco, USA  
Callum Fraser, University of Dundee, Scotland  
Stephen Halloran, NHS Bowel Cancer Screening Prog., Uni. of Surrey, UK  
Graeme Young, Flinders University, Australia

**World Endoscopy Organization  
Colorectal Cancer Screening Committee  
Expert Working Group 'FIT for Screening'**



  
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**This morning's agenda**


- FIT Developments**
  - Since the last EWG meeting (Berlin, October 2013)
- Stability**
  - Review of current evidence and strategies for minimising clinical impact
- FIT Cut-off**
  - Selection of cut-off faecal Hb concentration(s) for screening
- FIT in the US**
  - Building interest in the use of FIT in the US
- Open session**

  
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**Summary report**  
**4th meeting of the EWG 'FIT for Screening'**  
**Berlin, October 2013**

**Available at:**  
<http://www.worldendo.org/fit-for-screening-meeting-reports.html>

  
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**'EWG' publications – updated (08-04-14)**

- Fraser CG, Allison JE, Young GP, Halloran SP, Seaman HE. Improving the reporting of evaluations of faecal immunochemical tests for haemoglobin: the FITTER standard and checklist. *European Journal of Cancer Prevention* **2014**. Epub 27 February 2014.
- Fraser CG, Allison JE, Young GP, Halloran SP, Seaman HE. A Standard for Faecal Immunochemical Tests for Haemoglobin Evaluation Reporting (FITTER) (Letter). *Annals of Clinical Biochemistry* **2014**;51(2):301-2.
- Allison JE, Fraser CG, Halloran SP, Young GP. Population screening for colorectal cancer means getting FIT. The past, present, and future of colorectal cancer screening using FIT. *Gut and Liver* **2014**;8:117-30.
- Carroll MRR, Piggott C, Pearson S, Seaman HE, Halloran SP. Evaluation of quantitative faecal immunochemical tests for haemoglobin. Guildford, UK: Guildford Medical Device Evaluation Centre (GMEC), **November 2013**.
- Fraser CG, Allison JE, Young GP, Halloran SP. Quantitation of hemoglobin improves fecal immunochemical tests for noninvasive screening. *Clinical Gastroenterology and Hepatology* **2013**;11(7):839-40. (Citations: 5)
- Fraser C, Halloran S, Allison J, Young G. Making colorectal cancer screening FITTER for purpose with quantitative faecal immunochemical tests for haemoglobin (FIT). *Clinical Chemistry and Laboratory Medicine* **2013**;51(11):2065-7. (Citations: 3)
- Young GP, Fraser CG, Halloran SP, Cole S. Guaiac based faecal occult blood testing for colorectal cancer screening: an obsolete strategy? *Gut* **2012**;61(7):959-60. (Citations: 10)
- Fraser CG, Allison JE, Young GP, Halloran S. Newer fecal tests: opportunities for professionals in laboratory medicine. *Clinical Chemistry* **2012**;58(6):963-5. (Citations: 9)
- Fraser CG, Allison JE, Halloran SP, Young GP. A proposal to standardize reporting units for fecal immunochemical tests for hemoglobin. *J Natl Cancer Inst* **2012**;104(11):810-4. (Citations: 18)
- Allison JE, Fraser CG, Halloran SP, Young GP. Comparing fecal immunochemical tests: improved standardization is needed. *Gastroenterology* **2012**;142(3):422-4. (Citations: 22)

  
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**Publication of FIT Evaluation  
for NHS Bowel Cancer Screening Programme**

Carroll MRR, Piggott C, Pearson S, Seaman HE, Halloran SP. Evaluation of quantitative faecal immunochemical tests for haemoglobin. Guildford, UK: Guildford Medical Device Evaluation Centre (GMEC), November 2013.

**The four FIT systems selected were:**

- HM-JACKarc, Kyowa Medex Co Ltd, Japan
- NS-Plus Hb, Alfresa Parma Corp, Italy
- OC-Sensor DIANA, Eiken Chemical Co. Ltd, Japan
- FOB Gold NG, Sentinel CH. SpA, Italy/ using the BioMajesty analyser, Sysmex UK

**Full report is available at:**  
<http://www.worldendo.org/fit-ewg-publications.html>

  
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**Stability**

**Review of current evidence and strategies for  
minimising clinical impact**

**Co-Chairs: Stephen Halloran and Graeme Young**

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**Australian Government**  
Department of Health and Ageing

**MEDIA STATEMENT**

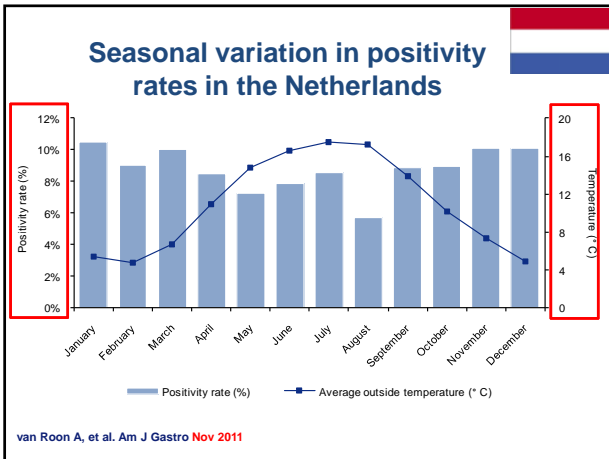
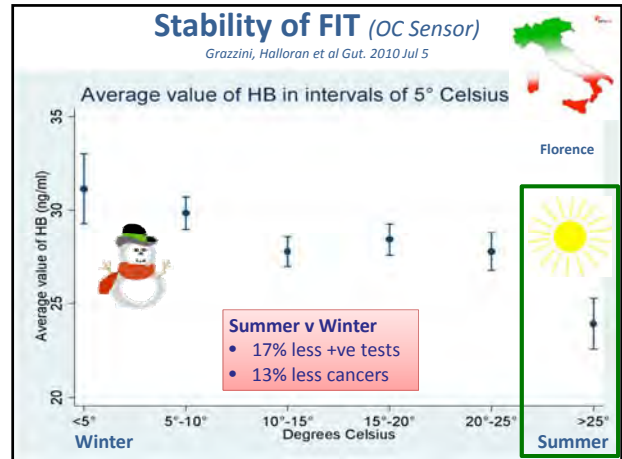
11<sup>th</sup> May 2009

**Self-Test Bowel Cancer Kits – Important Notice For Users**

The Department of Health and Ageing will start contacting participants in the National Bowel Cancer Screening Program from this week to invite people to re-take the test, after quality issues were identified during an investigation of the test kits.

The Department has recently observed that the level of positive results in tests performed since 1 December 2008 is lower than expected. The Department has reviewed the reliability of the test kits under certain conditions.

108,000 people have undertaken tests since this time and have returned a negative result and will be asked to repeat the test with a new kit. The Department will write to all 475,000 people who have received the test kits since 1 December 2008, although many have not yet used the test and returned it for assessment.

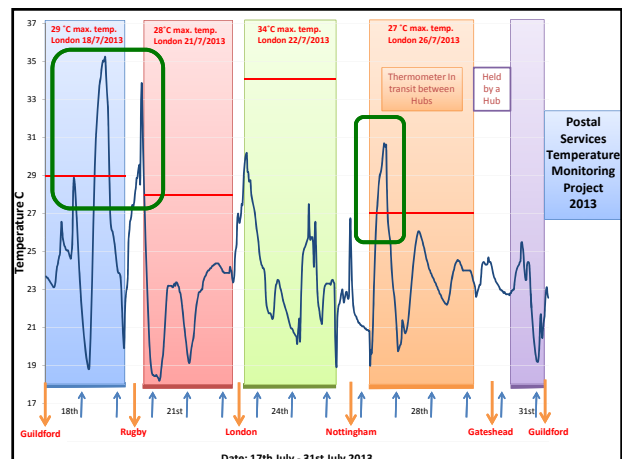
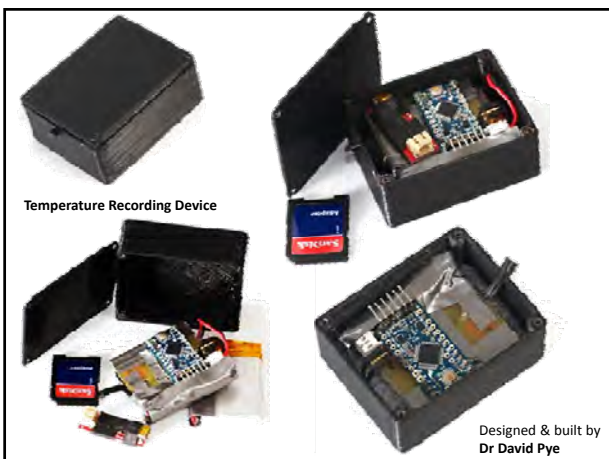


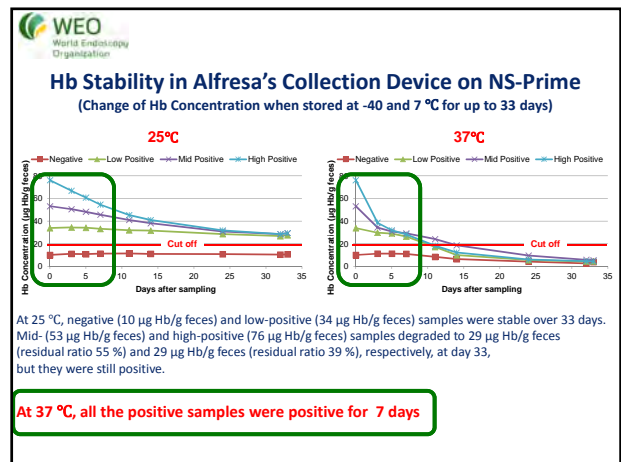
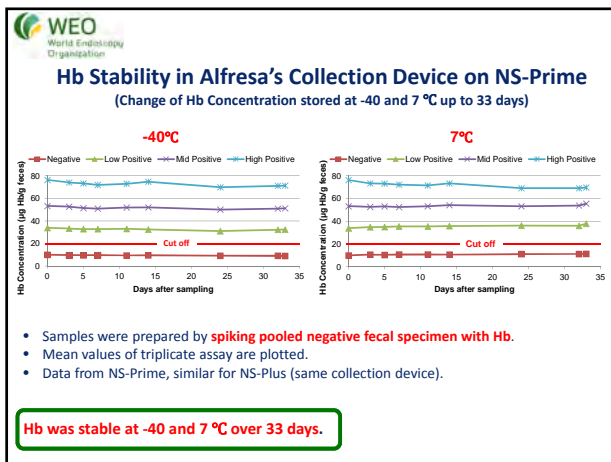
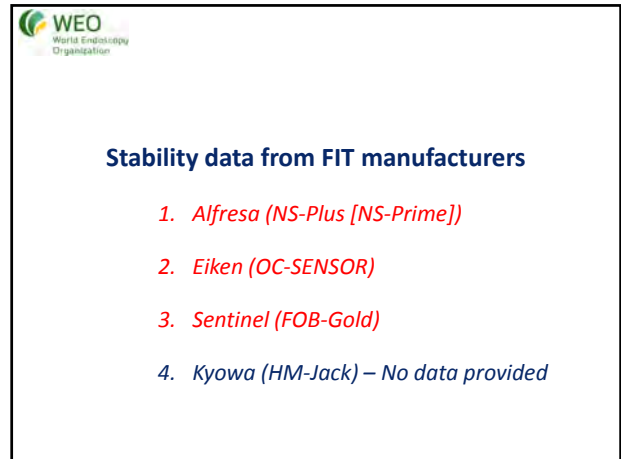
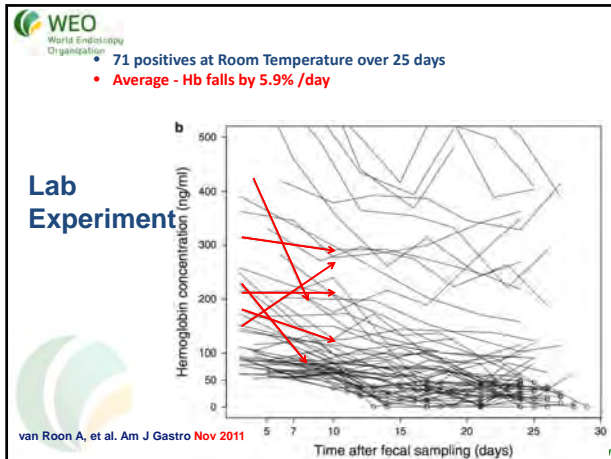
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**Stability**

**Review of current evidence and strategies for minimising clinical impact**

**Stephen Halloran**





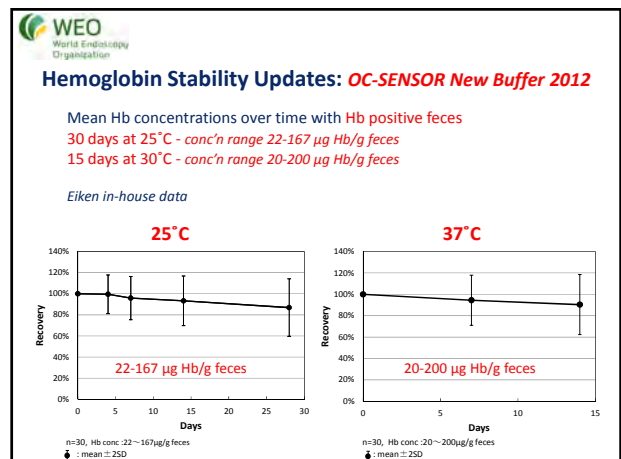
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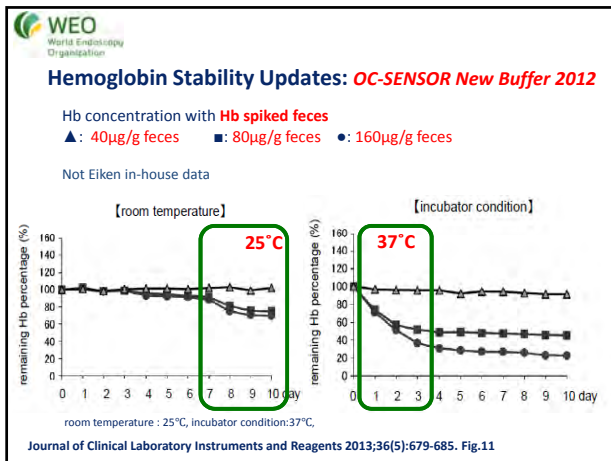
**Alfresa Summary - Hb Stability After Sample Collection**  
(Hb residual ratio when stored at -40, 7, 25, and 37 °C for up to 33 days)

	Negative	Low Positive	Mid Positive	High Positive
	10 <sup>(1)</sup>	34 <sup>(1)</sup>	53 <sup>(1)</sup>	76 <sup>(1)</sup>
at -40°C over 33 days	> 90%	> 90%	> 90%	> 90%
at 7°C over 33 days	> 90%	> 90%	> 90%	> 90%
at 25°C over 14 days	> 90%	> 90%	> 70%	> 50% <sup>(2)</sup>
at 37°C over 7 days	> 90%	> 70%	> 50% <sup>(2)</sup>	> 30% <sup>(2)</sup>

<sup>(1)</sup> Hb concentration (µg Hb/g feces) at day 0.  
<sup>(2)</sup> Hb residual ratios decreased to 37-55%, but the results were still positive.

Hb residual ratio was more than 90% in all the samples over 33 days when stored at -40°C and 7°C.  
Hb residual ratios were 72% and 54% in mid- and high-positive samples, respectively, when stored at 25°C for 14 days.  
Hb residual ratios were 78%, 55%, and 37% in low-, mid-, and high-positive samples, respectively, when stored at 37°C for 7 days.





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### FOB Gold® NG (Sentinel Diagnostics)

#### FAECAL HB STABILITY: BETWEEN EXPECTATIONS AND REALITY

- The FOB Gold® Tube Screen and the FOB Gold® NG (Sentinel Diagnostics) pick up approximately 10 mg of faeces which is added to 1.7 mL extraction buffer.
- The two faecal sampling devices are identical but use different preservative buffers (**New Buffer H, BH** and **Old Buffer N, BN**)

- FOB Gold® Tube Screen contains 1.7 mL of extraction solution (**BH, new buffer**)
- FOB Gold® Tube NG contains 1.7 mL extraction solution (**BN, old buffer**)

Improving the preservative buffer is of fundamental importance especially in the screening program

